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TROY, MI 48007-7021			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,8,10,12,13,21,27,30,31,36-38,40,42,43,45,48,49,51-53,57,60-68,70 and 71.

DETAILED ACTION

Claims 1-3, 8, 10, 12, 13, 21, 27, 30, 31, 36-38, 40, 42, 43, 45, 48, 49, 51-53, 57, 60-68, 70 and 71 are pending in this application, Claims 27, 36-38, 40, 42, 43, 45, 48, 49, 51-53, 57, 60-67 and 70 are acknowledged as withdrawn, Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 were examined on their merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, 10, 13, 30, 31, 68 and 71 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Katerkamp *et al.* (US 6,730,471 B1) for reasons of record set forth in the Prior Action.

Response to Arguments

Applicant's arguments filed 09/17/09 have been fully considered but they are not persuasive.

The Applicant argues that the Katerkamp *et al.* reference teaches a particular gradient of oxygen concentration but does not discuss a diffusion gradient. Applicant initially asserts a diffusion gradient to be a result of a metabolite being transported through a medium by diffusion only and defined as a gradient in concentration of a substance as a function of distance through a medium and that a diffusion gradient throughout a medium of a gas (oxygen) is depicted graphically as a straight line in a coordinate system having distance and concentration on two axes (Remarks, Pg. 11, Lines 17-19, Pg. 12, Lines 1-6 and Pg. 13, Lines 1-5 and Figures 1 and 4). Applicant cites Figs. 2 and 6 of the Katerkamp *et al.* reference as showing a coordinate system wherein the distance from bottom is shown on the x-axis and oxygen concentration is shown on the y-axis and wherein the oxygen concentration is not a linear function of the distance from the bottom and throughout the medium. Applicant argues therefore that Katerkamp *et al.* does not teach a culture device such that an oxygen diffusion gradient is established and does not teach or suggest the establishment of a diffusion gradient throughout the medium.

Applicant further alleges that the principle of Katerkamp *et al.* does not work through establishment of an oxygen diffusion gradient and it would not therefore be obvious to use said reference when discussion obviousness (Remarks, Pgs. 14-16).

This is not found to be persuasive for the following reasons, the instant invention is a device comprising at least one compartment being defined structurally by a diffusion

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barrier and having a transverse dimension of less than 1.5mm and being capable of retaining a medium and a substantially spherical metabolizing particle and at least one detector. The claim further contains functional language requiring that the diffusion barrier restrict and reduce the diffusive flux of metabolites to and from the substantially spherical metabolizing particle, allowing metabolite transport through the diffusion barrier to the substantially spherical metabolizing particle by means of diffusion where the medium in the compartment is stagnant and does not mix by turbulent flow so as to establish a linear metabolite diffusion gradient from the substantially spherical metabolizing particle and throughout the medium in the compartment. As discussed in the Prior Action, Katerkamp *et al.* teaches a culture device for monitoring metabolic activity comprising a MicrowellTM plate (Column 5, Lines 31-37), wherein each cylindrical well is defined by an oxygen permeable membrane (Column 8, Lines 19-23 and Fig. 5), a stagnant culture medium (inherently having a viscosity greater than or equal to water) such that an oxygen diffusion gradient is established (Column 8, Lines 30-35 and Fig. 6) and an oxygen detector comprising an oxygen sensitive membrane (Columns 10 and 11, Claims 1-2).

Therefore, the Examiner maintains that Katerkamp *et al.* meets the structural limitations of the instant invention and while some functional differences may arise in the manner of use, the reference nevertheless meets the claimed structural limitations. That the graphical representations of the diffusion gradients (function) obtained when in actual use are not exactly the same does not diminish the structural similarities between the two devices. The MPEP states:

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A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board’s finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

Applicant’s allegation that Katerkamp *et al.* does not work through the principle of establishing an oxygen diffusion gradient is not found to be persuasive as the reference makes numerous references to just such a principle, see Column 2, Lines 20-40, Column 8, Lines 28-35 as well as Figures 2 and 6.

Applicant argues that the structure of the Katerkamp *et al.* device would not function to provide such a diffusion gradient as claimed, and cites the references use of an oxygen permeable covering as distinguished from the claimed diffusion barrier which

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functions to restrict and reduce the diffusive flux of metabolites to and from the substantially spherical metabolizing particle (Remarks, Pg. 16, Lines 6-20).

This is not found to be persuasive for the following reasons, as discussed above the instant invention is a device comprising at least one compartment being defined by a diffusion barrier arranged around a substantially spherical metabolizing particle. The Katerkamp *et al.* reference teaches a device comprising a cylindrical well which is defined by an oxygen permeable membrane which (when in use) elicits a particular gradient of oxygen during oxygen consumption caused by metabolic activity (Column 8, Lines 30-35). The Examiner has interpreted this property as restricting and reducing the diffusive flux of metabolites (oxygen) to and from the substantially spherical metabolizing particle (cells). In any event, the instant invention must be distinguished structurally from the cited Prior Art and limitations directed to the function of the device when in use are insufficient to affect said distinguishing.

The MPEP states:

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &*

Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Katerkamp *et al.* (US 6,730,471 B1) in view of Barker *et al.* (US 5,652,142) for reasons of record set forth in the Prior Action.

Response to Arguments

Applicant's arguments filed 09/17/09 have been fully considered but they are not persuasive.

Applicant argues that the Barker *et al.* patent was cited for its teaching of an insert used in a cell culturing system which may be positionable within a cell culturing system and its relation to the embodiments of the instant invention wherein an insert may be used for adjusting the dimensions of a culture well. Applicant cites the Barker *et al.* reference as not teaching any system or method for the establishment of a diffusion gradient, nor show any structure which would do so. Applicant asserts that combining the culture device of Katerkamp *et al.* with the cell culture insert device of Barker *et al.* would not be applicable given the alleged deficiencies discussed, and the fact that Barker *et al.* in no way shows or suggests any structure for developing any type of diffusion gradient and in particular a linear metabolite diffusion gradient as required by the instant claims (Remarks, Pg. 17, Lines 4-18).

This is not found to be persuasive for the following reasons, as discussed above, Katerkamp *et al.* meets the structural limitations of the instant invention and while some functional differences may arise in the manner of use, the reference nevertheless meets the claimed structural limitations. The MPEP states:

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

"[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

The Barker *et al.* patent was cited for its teaching of an insert used in a cell culturing system which may be positionable within a cell culturing system and its relation to the embodiments of the instant invention wherein an insert may be used for adjusting the dimensions of a culture well, not for any teaching regarding a diffusion gradient and as such remains pertinent Prior Art.

Conclusion

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

10/30/09

/Rebecca E. Prouty/
Primary Examiner,
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